

REMARKS/ARGUMENTS

Claim 1 has been amended to recite that the permeate solution comprises an organic fluid that is substantially immiscible with water, incorporating the subject matter of claims 3 and 4. Claims 3 and 4 have been cancelled, and the dependencies of the remaining claims have been adjusted. Accordingly, no new matter is introduced in making these amendments.

Claims 1, 5, 8-9, and 11-13 remain in the application.

Claims 1, 3-5, 9, 12, and 13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al. (Zhu). This rejection is respectfully traversed for the following reasons.

First, claim 1 requires, *inter alia*, that the method use a membrane made from a hydrophobic material having a hydrophilic feed side and a permeate side, wherein the permeate side of the membrane has a water contact angle of greater than 90° and the feed side has a water contact angle of less than 70°. Zhu does not disclose such a membrane.

Zhu discloses a hydrophilic PVDF, low protein binding membrane (paragraph 2.2). Such membranes are hydrophilic on both the feed side and the permeate side of the membrane. Water readily wets the surface of both sides of such membranes, having a water contact angle of less than 70°. The Examiner contends, referring to paragraph 2.2 at page 400, that "the receptor-side of this membrane is coated with lecithin in dodecane—which makes the receptor (or permeate-side) hydrophobic." However, paragraph 2.2 at page 400 reads as follows:

In an artificial membrane permeability experiment, a 96-well filtration plate (hydrophilic PVDF, low-protein binding, Millipore, Bedford, MA) was used for the artificial membrane support and as the receiver plate. The filter material in each well of the filtration plate was wetted with 5 μ L of the artificial membrane solution, which consisted of 1% egg lecithin in n-dodecane. Then the filtration plate was securely placed on top of a donor plate (Dynex, Middlesex, UK) which was pre-filled with donor solutions (100-200 μ M drug solution in phosphate buffer, pH 5.5 or 7.4) in each well. Equal volumes of blank receiving solution were quickly added to the wells of the filtration plate.

Thus, Zhu discloses that “the filter material” in each well are “wetted” with the lecithin in dodecane solution. This does not suggest or imply that only the receptor-side of the membrane is coated with the hydrophobic “artificial membrane solution.” Indeed, one skilled in the art would realize that wetting a hydrophilic PVDF filter material with this solution would result in a hydrophobic surface on both the feed-side and the permeate-side of the membrane—not just the permeate side, as asserted by the Examiner.

Claim 1 as amended also requires that the permeate solution comprise an organic fluid that is substantially immiscible with water. Zhu does not disclose or suggest this. Referring again to Zhu paragraph 2.2 above, the donor solution (i.e., the feed solution) is drug in a phosphate buffer at pH 5.5 or 7.4. Zhu states that “volumes of blank solution” are then added to the wells of the filtration plate (that is, to the receiving or permeate solution). One skilled in the art would understand that a “blank” solution is the same aqueous phosphate buffer solution as used in the feed, but containing no drug. Thus, the permeate solution is an aqueous solution, and not an organic fluid, as required by claim 1.

The Examiner contends that the permeate solution in Zhu is octanol, referring to the introduction on page 399 and to paragraph 2.4 on page 401. However, these

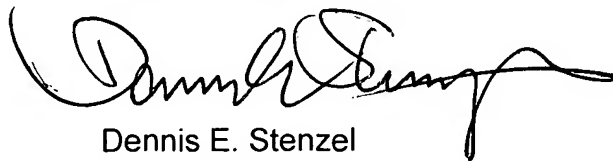
sections refer to octanol-water partition coefficients and to octanol-buffer distribution coefficients, respectively. They do NOT refer to the permeate solution.

Because Zhu is missing the microporous membrane made from a hydrophobic material that has a hydrophilic feed side of claim 1 and the permeate solution of claim 1, there can be no anticipation, and claim 1 is novel with respect to Zhu. Since all the remaining claims ultimately depend from claim 1, they are likewise novel with respect to Zhu.

Claims 1, 3-5, 8, 9, and 11-13 stand rejected under 35 U.S.C. 103(a) as being obvious over Zhu in combination with Kallury US 7,468,281 (Kallury). Kallury discusses the use of hollow-fiber membranes for the purification, concentration, and analysis of samples (abstract). However, neither Zhu nor Kallury disclose, teach, or suggest the use of a microporous membrane made from a hydrophobic material that has a hydrophilic feed side, nor the use of a permeate solution comprising an organic fluid that is substantially immiscible with water. Because of this, amended claim 1 would not have been obvious over Zhu in combination with Kallury. The remaining claims depend from amended claim 1, and are likewise not obvious over Zhu in combination with Kallury.

Early and favorable reconsideration is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Dennis E. Stenzel", with a stylized, flowing script.

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